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EXAMINER	
THANGAVELU, KANDASAMY	
ART UNIT	PAPER NUMBER
2123	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,637	ARAM ET AL.	
	Examiner	Art Unit	
	Kandasamy Thangavelu	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/13/04, 10/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-43 of the application have been examined.

Information Disclosure Statement

2. Acknowledgment is made of the information disclosure statements filed on December 13, 2004 and October 21, 2005 together with a list of the patents. The patents have been considered.

Drawings

3. The drawings submitted on March 23, 2004 are accepted.

Specification

4. The disclosure is objected to because of the following informalities:

Page 29, Line 6, "A method system for developing a solid model data" appears to be incorrect and it appears that it should be "A method for developing a solid model data".

Appropriate correction is required.

Claim Objections

5. The following is a quotation of 37 C.F.R § 1.75 (d)(1):

> The claim or claims must conform to the invention as set forth in the remainder of the specification and terms and phrases in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.

6. There are duplicate claims with same claim number of 19. The applicants' attention is requested to MPEP 608.01 (i) (f) which states that if there are several claims they shall be numbered consecutively in Arabic numerals.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

8.1 Claim 1 states, "A system for designing joint artificial implant components comprising:

an anthropometric data analyzer ...;

an implant model generator for generating at least one set of model data ...; and

a kinematic model simulator ... the kinematic model simulator generates dynamic response data ...".

The claim involves a system for designing joint artificial implant. The system does not produce any useful, tangible and concrete results and therefore is not statutory and cannot be patented under 35 USC 101. To produce useful, tangible and credible results, the system should display some of the results on a display terminal or save the results in a file for use in analysis and design.

In addition, the system as claimed comprises only software. If all parts of a system are software, then the system becomes descriptive material and is not statutory and cannot be patented under 35 USC 101. The system should include some hardware elements to be statutory and patentable.

Claims 2-17 depend on claim 1 but do not produce any useful, tangible and concrete results and therefore are not statutory and cannot be patented under 35 USC 101.

8.2 Claim 18 states, "A method for designing joint artificial implant components comprising:

analyzing anthropometric image data ...;

generating at least one set of implant model data ...; and

incorporating a set of implant model data in a kinematic simulation ...".

The claim involves a method for designing joint artificial implant components. The method does not produce any useful, tangible and concrete results and therefore is not statutory and cannot be patented under 35 USC 101. To produce useful, tangible and credible results, the method should display some results on a display terminal or save the results in a file for use in analysis and design.

Claims 19-31 depend on claim 18 but do not produce any useful, tangible and concrete results and therefore are not statutory and cannot be patented under 35 USC 101.

8.3 Claim 32 states, "A system for developing solid model data from joint motion image data comprising:

a motion data analyzer for analyzing joint motion image data ...;

an anthropometric data analyzer for generating geometric dimensions ...;

an artificial implant model generator for generating an artificial implant model ...".

The claim involves a system for developing solid model data from joint motion image data. The system does not produce any useful, tangible and concrete results and therefore is not statutory and cannot be patented under 35 USC 101. To produce useful, tangible and credible results, the system should display some of the results on a display terminal or save the results in a file for use in analysis and design.

In addition, the system as claimed comprises only software. If all parts of a system are software, then the system becomes descriptive material and is not statutory and cannot be

patented under 35 USC 101. The system should include some hardware elements to be statutory and patentable.

Claims 33-37 depend on claim 32 but do not produce any useful, tangible and concrete results and therefore are not statutory and cannot be patented under 35 USC 101.

8.4 Claim 38 states, "A method for developing solid model data from joint motion image data comprising:

analyzing joint motion image data to group image studies ...;

generating an artificial implant model from the geometric dimensions ...; and

simulating a kinematic model using the generated artificial implant model...".

The claim involves a method for developing solid model data from joint motion image data. The method does not produce any useful, tangible and concrete results and therefore is not statutory and cannot be patented under 35 USC 101. To produce useful, tangible and credible results, the method should display some results on a display terminal or save the results in a file for use in analysis and design.

Claims 39-43 depend on claim 38 but do not produce any useful, tangible and concrete results and therefore are not statutory and cannot be patented under 35 USC 101.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-9, 12-33 and 38-39 are rejected under 35 U.S.C. § 102(b) as being anticipated by **DiGioia, III et al.** (U.S. Patent 6,205,411).

10.1 **DiGioia, III et al.** teaches computer assisted surgery planner and intra-operative guidance system. Specifically, as per claim 1, **DiGioia, III et al.** teaches a system for designing joint artificial implant components (Abstract, L1-2; CL4, L67 to CL5, L1; CL7, L17-18), comprising:

an anthropometric data analyzer for identifying a plurality of geometric dimensions and a range of values for the identified dimensions (Fig. 2, Item 40; CL2, L56-58; CL6, L58-61);

an implant model generator for generating at least one set of model data representative of the identified geometric dimensions and a group of values with the range of values for the identified dimensions (Abstract, L4-5; Fig. 1, Item 12; Fig. 2, Item 42; CL2, L58-61; CL4, L67 to CL5, L1; CL5, L64-67; CL6, L58-61; CL7, L17-18); and

a kinematic model simulator for incorporating a set of model data in a kinematic model of a joint (Abstract, L5-7; Fig. 1, Item 14; Fig. 2, Item 44; CL5, L67 to CL6, L5), so that the kinematic model simulator generates dynamic response data corresponding to a set of model data (Fig. 2, Item 44 and Item 46; CL2, L67 to CL3, L4; CL5, L1-3; CL6, L2-3; CL7, L19-26; CL7,

L46-53), whereby the dynamic response of an artificial implant corresponding to the set of model data may be evaluated (Fig. 2, Item 48; CL5, L64 to CL6, L5; CL1, L48-50; CL2, L67 to CL3, L4; CL3, L28-31; CL7, L46-53).

Per claim 2: **DiGioia, III et al.** teaches a dynamic response data analyzer to generate differential dimensional data for modifying the one set of model data in response to the dynamic response data (CL3, L5-9; CL4, L53-56; CL4, L67 to CL5, L3; CL6, L3-4; CL7, L19-26), indicating that implantation of the artificial implant corresponding to the set of model data produces a conditional parameter in the kinematic model of the kinematic model simulator (CL1, L45-50; CL2, L67 to CL3, L4; CL3, L28-31; CL4, L67 to CL5, L3).

Per claim 3: **DiGioia, III et al.** teaches that the implant model generator incorporates the differential dimensional data to generate a second set of model data (CL3, L5-9; CL4, L53-56; CL4, L67 to CL5, L3; CL6, L3-4; CL7, L19-26);

the kinematic model simulator incorporates the second set of model data within the kinematic model to generate dynamic response data (Abstract, L4-5; Fig. 1, Item 12; Fig. 2, Item 42; CL2, L58-61; CL4, L67 to CL5, L1; CL5, L64-67; CL6, L58-61; CL7, L17-18); and

the dynamic response data analyzer determines whether additional differential dimensional data are generated for modification of the second set of model data (CL1, L45-50; CL2, L67 to CL3, L4; CL3, L28-31; CL4, L67 to CL5, L3).

Per claim 4: **DiGioia, III et al.** teaches that the dynamic response data analyzer determines whether a set of model data that generates dynamic response data meets an acceptance parameter (CL4, L53-56; CL4, L67 to CL5, L3).

Per claims 5-7: **DiGioia, III et al.** teaches that the anthropometric data analyzer receives computed tomography (CT) data for analysis; the anthropometric data analyzer receives magnetic resonance image (MRI) data for analysis; and the anthropometric data analyzer is a static image data analyzer (CL3, L42-46; CL6, L50-58).

Per claims 8 and 9: **DiGioia, III et al.** teaches that the static image data analyzer is a computer aided design (CAD) program that enables an operator to select a feature in static image data for defining a geometric dimension and to measure the selected geometric dimension; and the static image data analyzer is an adaptation of a computer program that measures terrain topographic features (CL7, L1-12; CL6, L50-61).

Per claim 12: **DiGioia, III et al.** teaches that the patient model emulator uses fluoroscopic image data of a joint in motion to generate the emulation force parameters (CL8, L59-63).

Per claim 13: **DiGioia, III et al.** teaches that the kinematic model simulator is a computer program that applies emulation force parameters to an implant model to generate dynamic

response data (Fig. 2, Item 48; CL5, L64 to CL6, L5; CL1, L48-50; CL2, L67 to CL3, L4; CL3, L28-31; CL6, L8-12; CL7, L46-53).

Per claim 14: **DiGioia, III et al.** teaches that the dynamic response data analyzer compares the dynamic response data generated by the kinematic model simulator (Fig. 2, Item 48; CL5, L64 to CL6, L5; CL1, L48-50; CL2, L67 to CL3, L4; CL3, L28-31; CL6, L8-12; CL7, L46-53), to the fluoroscopic data used to generate the emulation force parameters (CL8, L59-63) to evaluate the set of model data (Fig. 2, Item 48; CL5, L64 to CL6, L5; CL1, L48-50; CL2, L67 to CL3, L4; CL3, L28-31; CL6, L8-12; CL7, L46-53).

Per claim 15: **DiGioia, III et al.** teaches that the dynamic response data analyzer receives motion data in the time domain from the kinematic model simulator (CL3, L28-31; CL4, L53-56; CL7, L46-53).

Per claim 16: **DiGioia, III et al.** teaches that the dynamic response data analyzer generates a set of differential data to alter the set of model data (CL3, L5-9; CL4, L53-56; CL4, L67 to CL5, L3; CL6, L3-4; CL7, L19-26).

Per claim 17: **DiGioia, III et al.** teaches that a motion data analyzer for analyzing joint motion image data studies to group the studies into sets that are correlated by the degree of motion demonstrated during a particular activity (CL4, L53-56; CL5, L67 to CL6, L5; CL7, L34-40; CL7, L46-53), and

the anthropometric data analyzer identifies a plurality of geometric dimensions and a range of values for the identified dimensions for the joints imaged in a set (Fig. 2, Item 40; CL2, L56-58; CL6, L58-61).

10.2 As per Claims 18-19, 19-22, 24-25 and 28-29, these are rejected based on the same reasoning as Claims 1-6, 8-9, 13 and 15 supra. Claims 18-19, 19-22, 24-25 and 28-29 are method claims reciting the same limitations as Claims 1-6, 8-9, 13 and 15 as taught throughout by **DiGioia, III et al.**

Per claim 23: **DiGioia, III et al.** teaches that the anthropometric data analysis includes analysis of three dimensional image data (CL6, L50-58).

Per claim 26: **DiGioia, III et al.** teaches that the implant model data generation includes modifying the set of implant model data with image data of a joint physiology in dynamic motion (CL3, L5-9; CL4, L53-56; CL4, L67 to CL5, L3; CL6, L3-4; CL7, L19-26; CL3, L28-31; CL6, L50-58).

Per claim 27: **DiGioia, III et al.** teaches that the implant model data modification includes modification using dynamic motion image data of a joint compiled by taking fluoroscopic images of a joint in motion (CL3, L28-31; CL4, L53-56; CL7, L46-53; CL8, L59-63; CL6, L50-58).

Per claim 30: **DiGioia, III et al.** teaches that the dynamic response data analysis includes identifying a conditional parameter (CL1, L45-50; CL2, L67 to CL3, L4; CL3, L28-31; CL4, L67 to CL5, L3).

Per claim 31: **DiGioia, III et al.** teaches that the dynamic response data analysis includes generating a set of differential dimensional data from the identified conditional parameter to alter the model data (CL3, L5-9; CL4, L53-56; CL4, L67 to CL5, L3; CL6, L3-4; CL7, L19-26), so that the likelihood of the conditional parameter occurring from an implantation of an artificial joint corresponding to the set of model data is reduced (CL1, L45-50; CL2, L67 to CL3, L4; CL3, L28-31; CL4, L67 to CL5, L3).

10.3 As per claim 32, **DiGioia, III et al.** teaches a system for developing solid model data from joint motion image data (Abstract, L4-5; Fig. 1, Item 12; Fig. 2, Item 42; CL2, L58-61; CL4, L67 to CL5, L1; CL5, L64-67; CL6, L58-61; CL7, L17-18), comprising:

a motion data analyzer for analyzing joint motion image data to group image studies according to range of motion and activity (CL3, L28-31; CL4, L53-56; CL7, L46-53);

an anthropometric data analyzer for generating geometric dimensions and measurement ranges for the geometric dimensions (Fig. 2, Item 40; CL2, L56-58; CL6, L58-61), the geometric dimensions and measurement ranges corresponding to the image studies in at least one group of image studies (Fig. 2, Item 40; CL2, L56-58; CL6, L58-61, CL6, L50-61);

an artificial implant model generator for generating an artificial implant model from the geometric dimensions and measurement ranges (Abstract, L4-5; Fig. 1, Item 12; Fig. 2, Item 42; CL2, L58-61; CL4, L67 to CL5, L1; CL5, L64-67; CL6, L58-61; CL7, L17-18); and

a kinematic model simulator (Abstract, L5-7; Fig. 1, Item 14; Fig. 2, Item 44; CL5, L67 to CL6, L5).

Per claim 33: **DiGioia, III et al.** teaches that the motion data analyzer receives fluoroscopic image data of a plurality of joints in motion (CL8, L59-63).

10.4 As per Claims 38 and 39, these are rejected based on the same reasoning as Claims 32 and 33, supra. Claims 38 and 39 are method claims reciting the same limitations as Claims 32 and 33 as taught throughout by **DiGioia, III et al.**

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **DiGioia, III et al.** (U.S. Patent 6,205,411) in view of **Elia** (U.S. Patent Application 2004/0071637).

13.1 As per claim 10, **DiGioia, III et al.** teaches the system of claim 1. **DiGioia, III et al.** does not expressly teach a patient model emulator for generating emulation force parameters to be used by the kinematic model emulator; and the patient model emulator uses image data of a joint in motion to generate the emulation force parameters. **Elia** teaches a patient model emulator for generating emulation force parameters to be used by the kinematic model emulator; and the patient model emulator uses image data of a joint in motion to generate the emulation force parameters (Page 9, Para 0082, L6-10). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the system of **DiGioia, III et al.** with the system of **Elia** that included a patient model emulator for generating emulation force parameters to be used by the kinematic model emulator; and the patient model emulator using image data of a joint in motion to generate the emulation force parameters, because that would allow to determine if the implant would be able to resist a force vector applied to the implant at a particular point and a particular orientation (Page 9, Para 0082, L6-10).

Allowable Subject Matter

14. Claims 34-37 and 40-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and the independent claims are rewritten to overcome 35 USC 101 rejections.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 571-272-3717. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez, can be reached on 571-272-3753. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to TC 2100 Group receptionist: 571-272-2100.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

K. Thangavelu
Art Unit 2123
March 10, 2007